

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
01-CV-12257-PBS AND 01-CV-339

**TRACK ONE DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS'
MOTION TO STRIKE THE DECLARATION OF ERIC M. GAIER, PH.D.**

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Preliminary Statement

Plaintiffs have moved to strike the expert declaration of Eric M. Gaier, Ph.D. (“Dr. Gaier”) on four grounds: (1) he allegedly has no experience in the pharmaceutical industry; (2) certain charts that appear in his declaration allegedly suffer from fundamental flaws; (3) he supposedly relied on the declaration of another expert, Mr. Steven Young, without doing any analysis of his own; and (4) there allegedly is no evidentiary support for his opinion that payors had knowledge of the spread between average wholesale prices (“AWPs”) and average sale prices (“ASPs”).

Plaintiffs’ motion is completely baseless. We show below that Dr. Gaier has ample background and experience to qualify as an economic expert in this case; the principles and methodology he applies are reliable -- indeed, they are far more widely accepted and reliable than the principles and methodology of plaintiffs’ expert, Dr. Raymond Hartman; he has not relied on Mr. Young for anything except background information about matters that are largely not in dispute; and there is extensive evidentiary support, cited by Dr. Gaier, for his conclusion that payors had knowledge of the spread between AWP and ASP. Plaintiffs’ motion is replete with mischaracterizations of the facts and the law and should be rejected out of hand.

Statement of Facts

The Track 1 defendants (“defendants”)¹ have proffered Dr. Gaier as an economic expert on the extent to which there are individual issues relating to causation.² Specifically, defendants have asked Dr. Gaier to express an opinion on whether -- assuming the allegations of the Amended Master Consolidated Class Action Complaint (“AMCC”) are true -- plaintiffs will

¹ The Track 1 defendants are the AstraZeneca Group, the BMS Group, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, the Johnson & Johnson Group and the Schering-Plough Group.

² Dr. Gaier also discusses the issue of ascertainability— i.e. whether class members can be identified without examining individual transactions.

be able to show that all or substantially all of the putative class members have been injured by the alleged fraudulent scheme, without examining individual transactions or calling individual class members to testify. Defendants believe that, as an economist, Dr. Gaier is well-qualified to analyze cause and effect and to testify whether causation can be demonstrated through common proof.

Dr. Gaier is a partner and founding member of Bates White, LLC (“Bates White”), an economic consulting firm that performs services for a variety of industries, including the pharmaceutical industry. (Gaier Decl. at 4, 52; Gaier Dep. Tr. 24-26.) Dr. Gaier received his Ph.D. in economics from Duke University and has taught economics courses at the undergraduate and graduate levels. (Gaier Decl. at 4.) He has been retained as an expert by NASA, as well as a telecommunications carrier, a class of medical residents, a medical device manufacturer, an alcoholic beverage producer, steel manufacturers, a rail transportation firm, an asbestos-product manufacturing firm, a retail sales company and an automobile manufacturer. (*Id.* at 52-53.) In addition, he has testified as an expert for a government agency in a pharmaceutical case and worked for the class plaintiffs in a case involving the vitamins industry. (*Id.* at 53-54.)

Contrary to what plaintiffs argue, Dr. Gaier has not opined that (1) reimbursement levels were “not correlated” to AWP; (2) the PBM market was “so competitive” that payors could leverage away the effects of the alleged scheme; and (3) there are terms in payors’ contracts with PBMs that would permit them to negotiate in order to “alleviate” the effects of the alleged scheme. (Class Plaintiffs’ Memorandum in Support of Their Motion to Strike (“Plfs’ Mot.”) at 3-4.) Rather, he has opined that reimbursement levels vary substantially and “in many instances” bear no relationship to the corresponding AWP in the sense that the pattern of reimbursements is different from the pattern exhibited by AWP’s -- *e.g.*, the AWP’s are constant,

while the reimbursement levels fluctuate significantly. (Gaier Decl. ¶¶ 23-25, 30.) He has also opined that further analysis is warranted to determine the underlying causes of this variation, and he has concluded that competition, knowledge of the spread and tradeoffs between reimbursement amounts and other contract terms can -- in individual cases -- enable payors to avoid the impact of the alleged scheme. (*Id.* ¶ 20.)

Significantly, plaintiffs' economic expert, Dr. Hartman, does not disagree with Dr. Gaier's conclusion that there is significant variability in reimbursement levels that can be affected by competition, knowledge and trade-offs between reimbursement amounts and other contract terms. (Hartman Rebuttal Decl. ¶¶ 45(c), 63, 72(b).) He simply assumes that all payors have been injured no matter what the variations were in their knowledge, their expectations, their ability to leverage competition or the prices they paid. (*Id.* at ¶¶ 45(e), 53-54, 61.)³ Unlike Dr. Hartman's declaration, Dr. Gaier's declaration is not based on assumptions; it is based on facts.⁴

Applicable Standard

Under Rule 702 of the Federal Rules of Evidence, a witness qualified as an expert may testify if "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case". In applying Rule 702, the district court performs a gate-keeping function by determining "whether the reasoning or methodology underlying the testimony is scientifically valid and [] whether that reasoning or methodology properly can be applied to the facts in the issue". *Seahorse Marine Supplies, Inc. v. Puerto Rico Sun Oil Co.*, 295 F.2d 68, 80 (1st Cir. 2002) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-

³ In this regard, Dr. Hartman contradicts his initial declaration and his deposition testimony, where he conceded that it is possible that a substantial number of class members may not have suffered any injury. (Hartman Decl. ¶ 36, Hartman Dep. Tr. 269-71, 287, 502-04, 513.)

⁴ At the time he had written his initial declaration, Dr. Hartman had not reviewed any claims data and had only skimmed one deposition in the case. (Hartman Dep. Tr. 91, 231, 536-37.)

93 (1993)). While plaintiffs appear to argue that their expert's declaration should be stricken only if it is "fatally flawed", *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 135 (2d Cir. 2001), and defendants' experts should be subjected to a full *Daubert* review, it does not matter: plaintiffs have not come close to meeting that standard. Dr. Gaier's declaration clearly rests on a reliable foundation and is relevant to the task at hand. *See Cipollone v. Yale Indus. Prods., Inc.*, 202 F.3d 376, 380 (1st Cir. 2000) (reliability and relevance are the key issues).

Argument

I.

DR. GAIER IS QUALIFIED TO TESTIFY AS AN EXPERT

Plaintiffs assert that Dr. Gaier has "no education or training regarding any aspect of the pharmaceutical industry". (Plfs' Mot. at 5.) As a factual matter, that is simply untrue. Healthcare was one of the fields that Dr. Gaier studied in his industrial organization classes in graduate school, and he has attended numerous ABA discussions and seminars concerning healthcare and pharmaceutical pricing matters. (Gaier Dep. Tr. 12, 15, 56-57.) He also has become knowledgeable about the pharmaceutical industry as a result of his work as a testifying expert in *District of Columbia v. CVS Corp.* and his work on the vitamins litigation, a major antitrust suit involving a number of pharmaceutical manufacturers. (*Id.* at 18-19, 29-32.)

Even if plaintiffs' claim that Dr. Gaier has no experience in the pharmaceutical industry was factually correct, it would be irrelevant. Defendants are not calling Dr. Gaier as an expert witness on the pharmaceutical industry; they are calling him as an expert economist. "[L]ack of extensive practical experience directly on point does not necessarily preclude [an] expert from testifying. A formal education in a particular field is sufficient to qualify a witness as an expert". *TC Sys. Inc. v. Town of Colonie*, 213 F. Supp. 2d 171, 174-75 (N.D.N.Y. 2002) (citation omitted); *TFWS, Inc. v. Schaefer*, 183 F. Supp. 2d 789, 793 (D. Md. 2002), *rev'd on*

other grounds, 325 F.3d 234 (4th Cir. 2003) (expert economist's testimony as to general economic principles, as applied to alcoholic beverage industry, was well within his asserted realm of expertise and helpful even though he had no experience in alcoholic beverage industry).

Plaintiffs criticize Dr. Gaier on the ground that he "has never been asked to opine on issues related to class certification". (Plfs' Mot. at 7.) In addition to ignoring Dr. Gaier's work on class certification issues in a number of cases, even though he did not appear as the testifying expert (*see* Gaier Dep. Tr. 49-50, 204), plaintiffs again miss the point -- Dr. Gaier is not being called as an expert on class certification; he is being called as an expert economist to testify about causation.⁵ Furthermore, in contrast to plaintiffs' expert, who has testified in many class actions for plaintiffs' counsel, and has never submitted a report concluding that a class should not be certified (Hartman Dep. Tr. 37-38), Dr. Gaier has worked for both plaintiffs and defendants on class certification issues (Gaier Dep. Tr. 42, 49-50, 204).

Economists frequently testify as experts in cases involving a wide variety of industries. Their field of expertise is economics. If economists were required to be experts in particular substantive areas, as well as economics, before they could testify, very few of them would qualify as expert witnesses.⁶ Plaintiffs' effort to disqualify Dr. Gaier as an expert because he allegedly lacks experience in the pharmaceutical industry is patently frivolous.

⁵ Plaintiffs claim that Dr. Gaier "wholly failed to do what he was retained to do -- namely, he did not even attempt to determine whether damages could be calculated on a classwide basis". (Plfs' Mot. at 13.) Dr. Gaier was not retained to testify about damages -- although his conclusion that there are individual issues with respect to causation would also imply that there are individual issues with respect to damages.

⁶ Plaintiffs also criticize Dr. Gaier on the ground that he has never testified in a fraud or RICO case. (Plfs' Mot. at 8.) He is not being proffered as an expert on either fraud or RICO.

II.

DR. GAIER'S METHODOLOGY IS RELIABLE

Plaintiffs attack Dr. Gaier's methodology, first of all, because he did not review defendants' documents in preparing his declaration. (Plfs' Mot. at 8.) Once again, plaintiffs' criticism misses the point. Dr. Gaier's assignment was to analyze plaintiffs' and the class members' conduct, not defendants' conduct. He states in his declaration that he assumes, for purposes of his report, that plaintiffs' allegations with respect to defendants' conduct are correct. (Gaier Decl. at 6 n.2.) It is not necessary for him to review defendants' documents in order to determine whether there are individual issues affecting plaintiffs and the class.⁷

Plaintiffs also claim that Dr. Gaier's dispersion charts⁸ are unreliable because he failed to control for quantity when looking at reimbursement amounts; he failed to investigate when the data contained inexplicable outliers; and he failed to investigate phenomena such as an increase in the spread between AWP and ASP over time. (Plfs' Mot. at 2.) The latter criticism, once again, is beside the point. By assuming that the allegations of the AMCC are true, Dr. Gaier assumed that there was an increase in the spread over time; there was no need for him to investigate that independently. Plaintiffs' other criticisms of Dr. Gaier's methodology are also without merit.

As demonstrated by Dr. Gaier's Sur-Reply Declaration dated January 21, 2005 ("Gaier Sur-Reply Decl."), plaintiffs' claim that Dr. Gaier's charts are unreliable because he failed to control for quantity is completely without merit. To the extent that there may be

⁷ Plaintiffs also criticize Dr. Gaier for allegedly failing to locate an OIG report regarding the reporting of prices using AWP. (Plfs' Mot. at 9-10.) Dr. Gaier's declaration identifies dozens of publications on the pharmaceutical industry, including several OIG reports. (Gaier Decl. ¶ 54.) The particular report about which plaintiffs complain has absolutely no bearing on whether there are individual issues affecting the class.

⁸ The dispersion charts are designed to illustrate the relationship between individual reimbursements and AWPs.

quantity errors in the data Dr. Gaier used, they are insignificant. (Gaier Sur-Reply Decl. ¶ 47.) Indeed, when the data are adjusted to correct for quantity errors -- something that plaintiffs' expert, Dr. Hartman, did not do -- the dispersion charts are essentially unchanged. (*Id.* at Figure 5.)

Furthermore, contrary to what plaintiffs claim, Dr. Gaier in fact excluded outliers in his initial declaration. For example, in his Figure 1, he excluded 1,385 observations by limiting his data to amounts between \$0 and \$800, and he expressed his conclusions by reporting the range between the 5th and 95th percentiles. (Gaier Sur-Reply Decl. ¶ 43.) Dr. Gaier's methodology (i.e. excluding outliers) is virtually the same as Dr. Hartman's methodology in that regard; his technique (i.e. taking the 5th and 95th percentiles) may be different, but Dr. Gaier's technique results in a lower coefficient of variation (i.e. more likely to understate dispersion) than Dr. Hartman's technique. (*Id.* ¶ 43-44.)

In moving to exclude an expert's testimony, a party must do more than simply argue that the expert's approach is different from the approach that its expert would use. A party must demonstrate that the approach used by the expert in question renders the results unreliable. *See Estate of Bud Hill v. Conagra Poultry Co.*, No. CIV. A.4:94CV0198-HLM, 1997 WL 538887 at *8-9 (N.D. Ga. Aug. 25, 1997) (defendants failed to show expert's inclusion of outliers rendered his regression analysis invalid). Plaintiffs have utterly failed to do that here.

III.

DR. GAIER DID NOT IMPROPERLY RELY ON OTHER EXPERTS

Plaintiffs contend that Dr. Gaier's testimony should be excluded because he "merely regurgitates the opinions of Defendants' other experts, primarily Mr. Young" (Plfs' Mot. at 13-14.) While Dr. Gaier met with Mr. Young on a number of occasions, he does not rely on Mr. Young for any of the opinions expressed in his declaration. He does not even cite Mr. Young's declaration in his two declarations. (Gaier Sur-Reply Decl. ¶ 64.)

Furthermore, it should not be surprising that there are similarities between Dr. Gaier's and Mr. Young's understanding of the facts since they are both analyzing the same industry -- albeit from a different perspective. There are also similarities between Dr. Gaier's and Dr. Hartman's understanding of the facts.⁹ Indeed, most of the facts that are set forth in plaintiffs' three-page comparison of the declarations of Dr. Gaier and Mr. Young -- that many payors knew that AWP did not equal acquisition cost, payors understand that payment for drugs helps physicians pay for practice costs, payors negotiate with PBMs for a package of products and services, contractual terms are interdependent and payors can leverage competition -- are undisputed.

To the extent that Dr. Gaier testified that his discussions with Mr. Young -- an industry expert -- were useful in helping him to understand the pharmaceutical industry, that does not disqualify him as an economic expert. "An expert cannot be an expert in all fields, and it is reasonable to expect that experts will rely on the opinion of experts in other fields as background material for arriving at an opinion". *United States v. 1,014.16 Acres of Land*, 558 F. Supp. 1238, 1242 (W.D. Mo. 1983). "[W]hen an expert relies on the opinion of another, such reliance goes to the weight, not to the admissibility of the expert's opinion". *Ferrara & DiMercurio v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 9 (1st Cir. 2001).

Plaintiffs also take Dr. Gaier to task for criticizing Dr. Hartman's reliance on an article by James Langenfeld and Robert Maness which attempts to demonstrate that PBMs have conflicts of interest. (Plfs' Mot. at 19.) All Dr. Gaier did was point out that the Langenfeld and Maness article was not peer reviewed, and that its conclusions have been refuted in a subsequent

⁹ For example, both Dr. Gaier and Dr. Hartman conclude that knowledge of the alleged AWP scheme would protect payors from injury. (Hartman Decl. Attachment C at 15; Gaier Decl. ¶ 48.) Both experts also agree that PBMs serve many functions for payors and the contract terms between payors and PBMs vary as a result of negotiations between the parties. (Hartman Decl. Attachment C at 6, Hartman Reb. Decl. ¶ 72(b), Gaier Decl. ¶¶ 15, 61, 63.) They also recognize that physician services are bundled with physician-administered drugs. (Hartman Decl. Attachment C at 5, Gaier Decl. ¶¶ 62-63.) Both Dr. Hartman and Dr. Gaier also acknowledge that there is significant variation among class members with respect to bargaining power, size, information asymmetries and expectations. (Hartman Reb. Decl. ¶¶ 41, 44-45, 47-48, Gaier Decl. ¶¶ 10, 41-43, 49-53.)

peer reviewed article by Marta Wosinski and Robert Huckman. (Gaier Decl. ¶ 37.) Plaintiffs state that “Dr. Gaier did no independent analysis of the conclusions of that article” (Plfs’ Mot. at 19), but Dr. Hartman did no independent analysis of the article either. If a failure to perform an independent analysis of an article relied on in an expert report is a basis for disqualifying an expert, then Dr. Hartman should be disqualified, not Dr. Gaier, because Dr. Hartman is the one who relied on the article. (Hartman Decl. ¶ 14 & 14 n. 34, Attachment C at 10 & 12 n. 32).

The folly of plaintiffs’ position is further illustrated by their criticism of Dr. Gaier’s reliance on the conclusions of the FTC with respect to its extensive investigation into the competitiveness of the PBM industry. (Plfs’ Mot. at 19.) As Dr. Hartman admitted at his deposition, the FTC only reaches conclusions after reviewing thousands of pages of documents, taking testimony and engaging in substantial analysis. (Hartman Dep. Tr. 399-401.) The conclusions of regulatory agencies, who have access to nonpublic information, are often relied on by experts such as economists, and Dr. Gaier’s reliance on those conclusions is completely proper here. *See In re Custom Distribution Servs. Inc.*, 224 F.3d 235, 246-47 (3d Cir. 2000) (real estate appraiser may rely on letters from United States Environmental Protection Agency and New Jersey Department of Environment, indicating existence of environmental contamination, in valuation of property).¹⁰

IV.

THERE IS EVIDENTIARY SUPPORT FOR DR. GAIER’S CONCLUSION THAT PAYORS HAD KNOWLEDGE ABOUT THE ALLEGED INFLATION OF AWP

In his declaration, Dr. Gaier opines that many payors knew that AWP was not equal to the manufacturer’s selling price and, in some instances, they knew the magnitude of difference between AWP and ASPs. (Gaier Decl. ¶ 47.) Contrary to plaintiffs’ claim that there

¹⁰ Dr. Hartman, by contrast, rejects the FTC’s conclusions, without any analysis, and relies instead on an article by a former employee of the FTC. (Hartman Reb. Decl. ¶ 62, 70; Gaier Sur-Reply Decl. ¶ 20.)

is “no evidentiary support” for this opinion (Plfs’ Mot. at 3), Dr. Gaier meticulously supports that opinion with citations to the record. (Gaier Decl. ¶¶ 51-54, App. K.) It is well-established that an expert may support an opinion by citations to the record. *See, e.g., U.S. Info. Sys., Inc. v. IBEW*, 313 F. Supp. 2d 213, 237 (S.D.N.Y. 2004) (“It is well settled that an expert is free to offer testimony to provide a background for the case.”).

In an effort to buttress their argument, plaintiffs criticize Dr. Gaier for testifying that “*not a single witness in this case* has testified to knowing that AWP was manipulated and the spread manipulated to induce customers to purchase a pharmaceutical products [sic]”. (Plfs’ Mot. at 20; emphasis in original.) Dr. Gaier testified that way because no witness, in fact, has testified from personal knowledge that AWP and the spread were “manipulated” in any way. Rather, they have consistently testified that AWP is used as a benchmark or reference point for negotiating prices, and most contracts reflect discounts significantly below AWP. (Gaier Decl. ¶¶ 51-53, App. K.) Plaintiffs’ counsel were present at those depositions, but they failed to elicit testimony about “manipulation.” The complete failure of plaintiffs’ proof is hardly a reason to disqualify Dr. Gaier.

Conclusion

For the foregoing reasons, plaintiffs' motion to strike the declaration of Dr. Gaier should be denied.

Respectfully submitted,

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Dated: January 21, 2005

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by express mail on January 21, 2005.


Jessica V. Barnett

CERTIFICATE OF SERVICE

I, Joseph E. Haviland, certify that on February 4, 2005, I caused a true and correct copy of the foregoing document to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2, in the above-captioned proceeding by sending a copy to Verilaw Technologies for posting and notification to all parties.

/s/ Joseph E. Haviland

Joseph E. Haviland